

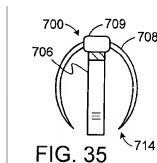
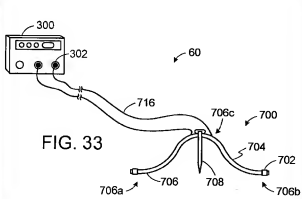
REMARKS

I. PRELIMINARY REMARKS

Claims 1, 2, 6, 8, 13, 16 and 28 have been amended. Claims 21-27 have been canceled. Claims 31-41 have been added. Claims 1-20 and 28-41 remain in the application. Claims 9-10 and 28-30 have been withdrawn from consideration. Reexamination and reconsideration of the application, as amended, are respectfully requested.

II. BRIEF DESCRIPTION OF AN EXEMPLARY EMBODIMENT

The present inventions, as defined by the claims, are directed generally to apparatus that may be used to stimulate tissue. Referring to Figures 33 and 35, which are reproduced below, the exemplary apparatus includes a pair of stimulation electrodes 702 that are carried by an anchor 704. The anchor 704 consists of a flexible pre-shaped carrier 706, with end portions 706a-b and a curved interior portion 706c, and a pair of tissue piercing members 708. During use, the carrier 706 will be deflected and stressed when the tissue piercing members 708 are pushed into tissue. The stress in the deflected carrier 706 will, in turn, force the electrodes 702 against the tissue because the tissue piercing members 708 prevent the curved interior portion 706c from pulling away from the tissue.



III. PRIOR ART REJECTIONS

A. The Rejections

Claims 1-8 and 11-21 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,277,117 to Tetzlaff ("the Tetzlaff patent"). As claim 21 has been canceled, it is respectfully submitted that the rejection thereof under 35 U.S.C. § 102 has been rendered moot. The rejection of the remaining claims under 35 U.S.C. § 102 is respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. The Tetzlaff Patent

The Tetzlaff patent discloses a mechanical forceps 20 and an electrode assembly 21 that may be removably secured to the mechanical forceps. The forceps 20 includes shaft portions 12 and 14 that are secured to end effectors 22 and 24 and are also pivotably connected to one another by a pin 25. The relative positions of the shaft portions 12 and 14 may be fixed by a ratchet. The ratchet includes ratchet portions 32 and 34 with inwardly projecting flanges 31 and 33. The electrode assembly 21 includes an electrode 110, with a substrate 111 and a conductive surface 116, and an electrode 120, with a substrate 121 and a conductive surface 126.

C. Discussion Concerning Claims 1-7, 11 and 12

Independent claim 1 calls for a combination of elements comprising "a carrier movable between an unstressed state and a deflected and stressed state," "a tissue stimulation element supported on the carrier" and "a tissue engagement device, associated with the carrier, ***configured to secure itself to tissue*** and secure the carrier to the tissue in the deflected and stressed state." The respective combinations

defined by claims 2-7, 11 and 12 include, *inter alia*, the elements recited in independent claim 1.

The Tetzlaff patent fails to teach or suggest the claimed combinations. For example, the Office Action has apparently taken the position that the Tetzlaff ratchet (i.e. ratchet portions 32 and 34) corresponds to the claimed "tissue engagement device." [Office Action at page 2.] The unreasonableness of such a claim interpretation notwithstanding, the Tetzlaff ratchet is not "configured to **secure itself to tissue** and secure the carrier to the tissue in the deflected and stressed state." The ratchet portions 32 and 34 secure themselves to one another, not tissue.

As the Tetzlaff patent fails to teach or suggest each and every element of the combination recited in independent claim 1, applicant respectfully submits that claims 1-7, 11 and 12 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

D. Discussion Concerning Claim 8

Independent 8 calls for a combination of elements including, *inter alia*, "a carrier," "a tissue stimulation element," and "first and second **tissue piercing members** associated with the carrier."

The Tetzlaff patent fails to teach or suggest the claimed combination. For example, the Office Action has apparently taken the position that the pointed tips of the Tetzlaff **ratchet flanges** 31 and 33, which are portions of the ratchet that keeps the shaft portions 12 and 14 from moving away from one another, correspond to the claimed "tissue piercing members." [Office Action at page 2.] Applicant respectfully submits that such an interpretation of the claim is well beyond the broadest reasonable interpretation, i.e. "the broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'" *Phillips v. AWH Corp.*, 75 USPQ2d 1321, 1329, (Fed. Cir. 2005), *citations omitted, emphasis added*. The pointed tips of the Tetzlaff ratchet flanges 31 and 33 do not engage tissue, let alone pierce it.

As the Tetzlaff patent fails to teach or suggest each and every element of the combination recited in independent claim 8, applicant respectfully submits that claim 8 is patentable thereover and that the rejection of claim 8 under 35 U.S.C. § 102 should be withdrawn.

E. Discussion Concerning Claims 13-15

Independent claim 13 calls for a combination of elements comprising “a tissue stimulation element” and “means ... **for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure and pressing the stimulation element against the single side of the tissue structure.**” The respective combinations defined by claims 14 and 15 include, *inter alia*, the elements recited in independent claim 13.

The Tetzlaff patent fails to teach or suggest the claimed combinations. For example, the apparatus disclosed in the Tetzlaff patent is a forceps that is secured to a tissue structure by engaging **both sides** of the tissue structure. [Note Figures 8 and 9.] As such, there is no structure disclosed in the Tetzlaff patent which performs the function recited in the means-plus-function element in independent claim 13.¹ The rejection of claims 13-15 under 35 U.S.C. § 102 should, therefore, be withdrawn.

F. Discussion Concerning Claims 16-20

Independent 16 calls for a combination of elements comprising “a tissue stimulation element” and “an anchor, associated with the tissue stimulation element, **configured to secure the surgical apparatus to the tissue by piercing the tissue** and press the stimulation element against the tissue.” The respective combinations defined by claims 17-20 include, *inter alia*, the elements recited in independent claim 16.

¹ Applicant notes that “the application of a prior art reference to a means or step plus function limitation **requires** that the prior art element **perform the identical function** specified in the claim.” [MPEP 2182, emphasis added.]

The Tetzlaff patent fails to teach or suggest the claimed combinations. For example, the Office Action has apparently taken the position that one of electrodes 110 and 120 corresponds to the "stimulation element" and that the Tetzlaff *ratchet flanges* 31 and 33, which are portions of the ratchet that keeps the shaft portions 12 and 14 from moving away from one another, correspond to the claimed "anchor." The Tetzlaff ratchet flanges 31 and 33 simply are not configured to secure any portion of the Tetzlaff forceps to tissue by piercing the tissue.

As the Tetzlaff patent fails to teach or suggest each and every element of the combination recited in independent claim 16, applicant respectfully submits that claims 16-20 are patentable thereover and that the rejection of claims 16-20 under 35 U.S.C. § 102 should be withdrawn.

IV. NEWLY PRESENTED CLAIMS 31-41

Newly presented claims 31-33 respectively depend from independent claims 1, 13 and 16 and are patentable for at least the same reasons as claims 1, 13 and 16.

Newly presented independent claim 34 calls for a combination of elements comprising "first and second tissue stimulation elements," "a flexible carrier movable between an unstressed state and a deflected and stressed state and including a first end portion that carries the first tissue stimulation element, a second end portion that carries the second tissue stimulation element, and a curved interior portion located between the first and second end portions and configured such that the curved interior portion will be in spaced relation to the tissue surface when the end portions are in contact with the tissue surface and the carrier is in the unstressed state" and "a tissue engagement device carried by the curved interior portion of the carrier between the first and second tissue stimulation elements and configured to secure the carrier to the tissue surface in the deflected and stressed state." Applicant respectfully submits that the Tetzlaff patent fails to teach or suggest such a combination and that claims 34-41 are patentable thereover.

V. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

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Date

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